Open Disclosure and Patient Safety

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Overview

- Legislative framework
- Proposed changes to legislation and patient safety
- Published guidance for hospitals and clinicians
- Government proposals for management of claims in relation to the CervicalCheck scandal

What is Open Disclosure?

Civil Liability (Amendment) Act 2017

- Duty of candour
- Voluntarily disclose that a "patient safety incident" has occurred
- "Patient safety incident" defined:
  - Unintended or unanticipated injury or harm to the patient
  - No actual injury or harm but service provider has reasonable grounds to believe patient has been put at risk of unintended or unanticipated injury or harm
  - "Near misses" also included

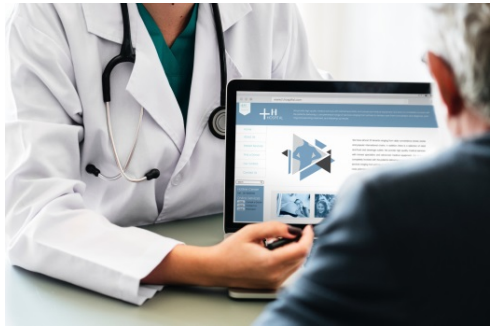
Legal Protection

Civil Liability (Amendment) Act 2017

- Open Disclosure shall not:
  - Constitute an express or implied admission of fault or liability in relation to a patient safety incident
  - Be admissible as evidence of fault or liability in relation to that patient safety incident
  - Constitute an express or implied admission of fault, professional misconduct, poor professional performance, unfitness to practice a health service, or other failure or omission
  - Invalidate or otherwise affect insurance cover

How to Communicate – Open Disclosure Meeting

Civil Liability (Amendment) Act 2017



- Information to be provided:
  - Description of patient safety incident
  - Date incident occurred
  - Manner in which patient safety incident came to attention
  - Information in respect of consequences (including likely)
  - Statement in writing to patient or next of kin

- Apology? Optional… “An expression of sympathy or regret”

- Disclosure procedures followed - to be documented

Pros and Cons of Open Disclosure

Pros

- Improve quality of healthcare
- Attacking the blame culture
- Systematic improvements
- Greater trust leading to a reduction in litigation
- Reduce defensive medicine

Cons

- Increase patient anxiety
- Increased costs of litigation
- Delaying justice and compensation

General Scheme of the Patient Safety Bill 2018

- Mandatory open disclosure where a "serious patient safety incident" occurs…
- "any unintended or unexpected incident or harm, including":
  - Death, permanent lessening of bodily, sensory, motor, physical or intellectual functions
  - Harm which is not severe but results in increased treatment, changes to the structure of the body, a shorter life expectancy, or impairment / pain likely to last 28+ days
  - Patient requiring treatment in order to prevent death or any injury which, if left untreated, would lead to one of the above
  - Further "serious patient safety incidents" may be prescribed by the Minister

General Scheme of the Patient Safety Bill 2018

- Procedure and protections same as in Civil Liabilities (Amendment) Act 2017
- “Near misses” not included
- SCA to analyse and publish anonymised information on reportable incidents
- Failure to mandatory disclose is an offence with up to €7,000 fine and 6 months imprisonment

Guidance for Professionals

- HSE Open Disclosure: National Policy
  - "*The service user must be informed in a timely manner of the facts relating to the incident and an apology provided, where appropriate.*"
  - *"When a clinician makes a decision, based on his / her clinical judgement, not to disclose to the service user that an adverse event has occurred…"*
- General theme of inconsistency in approach resulting in uncertainty for clinicians

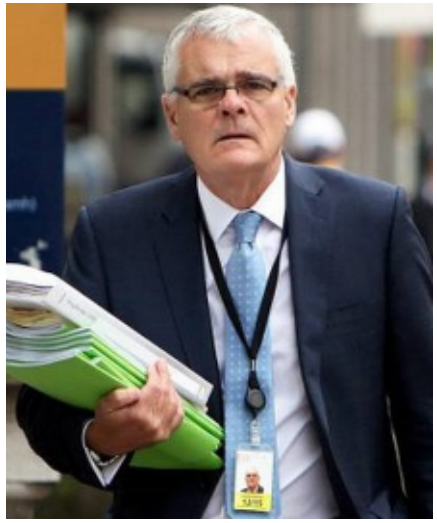
Guidance for Professionals

- Guide to Professional Conduct and Ethics for Registered Medical Practitioners (8th edition):
  - Support for open and honest communication
  - "Patients and their families, where appropriate, are entitled to honest, open and prompt communication about adverse events that may have caused them harm"
  - No definitive guidance on "where appropriate" to disclose information to patients

Smear Test Scandal

- Vicky Phelan settlement litigation
  - 2011 all clear given
  - 2014 audit showed abnormalities
  - 2017 221 women informed of falsely given all-clear
- Ongoing issues
  - Preliminary inquiry
  - Free smear test by GP or clinic
  - 6,000 repeat tests

CervicalCheck Tribunal Bill



- Report at the request of Simon Harris
- Legislation expected early-mid 2019
- Recommended key features:
  - Hearings be held in private
  - SOL to apply as normal
  - Chairperson to determine liability, damages and costs
  - Experts may assist chairperson if necessary
  - Fast-track system where liability not at issue
  - Right of full rehearing in High Court

Expert Group – Alternatives for Resolving Clinical Negligence Claims

- Consider alternative mechanisms to the court process for resolving clinical negligence claims in Ireland
- Focus areas for review:
  - Effectiveness of the law of torts and possible operational improvements in the legal framework
  - Alternatives to the courts such as 'no-fault' system
  - Roles of the HSE & State Claims Agency
  - Impact of the law of tort on patient safety and open disclosure
- Interim report expected shortly

Thank You

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